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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/572,502

03/17/2006

Nitin Bhalachandra Dharmadhikari

2867.003US1

4377

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04/06/2011

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1618

NOTIFICATION DATE

DELIVERY MODE

04/06/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@slwip.com

request@slwip.com

Office Action Summary	Application No. 10/572,502	Applicant(s) DHARMADHIKARI ET AL.	
	Examiner MICAH-PAUL YOUNG	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-31,34-40 and 42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-31,34-40 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/29/10 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25-31, 34-40 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Conte et al (USPN 6,294,200 hereafter '200) in view of Hayashida et al (USPN 5,593,694 hereafter '694).

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The '200 patent teaches a coated tablet comprising a core and a coating (abstract). The core comprises layers (Figures), comprises an active pharmaceutical component comprising excipients (col. 4, lin. 55-65; col. 7, lin. 53-col. 8, lin. 26) and a swelling components (col. 5, lin. 29-40). The swellable components comprise swellable components like cellulose wicking agents, osmogents like lactose, (col. 5, lin. 10-25). The formulation comprises a second active ingredient that is release in an immediate release form (part 5, col. 3, lin. 60-65). The coating surrounds the core layers with the swellable layer in contact with the coating (part 2, Figure 3). The swellable components are present as an in-lay tablet layer surrounding by the coating (Figures). Upon release, the immediate release portion is removed and exposes the core layers. The coating polymer is impermeable to the drug composition comprising cellulose phthalates (col. 6, lin. 25-45). The removed immediate release coating acts a passageway on the coating for the active agent to be released. The formulation is further coated with pH dependent coating (col. 7, lin. 10-20).

The '200 patent discloses an orally administerable drug delivery system comprising a core and a coating. The coating surrounds the core, where the core comprises active agent regions. The coating has a region is operable to be removed while the remaining coating does not dissolve. The reference is silent to the inclusion of semipermeable coatings. However, the inclusion of semipermeable coating is well known the art as seen in the '694 patent. The semipermeable coating is a blend of permeable and impermeable coating compounds that allow for water to permeate without disintegrating completely. These types of polymers are found in the '694 patent.

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The '694 patent teaches an oral administrable drug delivery system comprising a core and a coating (abstract). The core comprises an active ingredient along with an excipient (col. 5, lin. 60-col. 6, lin. 65). The core tablet further comprises swellable portions (col. 4, lin. 34-60). The core is surrounded by a coating that is in immediate vicinity of the drug and swellable portions. The periphery of the coated tablet is thinner than the top and bottom and upon administration will absorb water (col. 4, lin. 12-34). The coating is semipermeable to water around the edges (col. 7, lin. 10-20). The water absorption activates the water swellable portions of the core tablet forcing release of the active agent, while the top and bottom portions of the coating remain intact (Figures 2A, 2B). The sides of the coating are preselected to be removed after contact with the aqueous environment of the body, while the top and bottom portions are not removed (**Ibid.**) Since the tops and bottom of the dosage form does not dissolve or transmit drug to the aqueous environment, the side act as passageways for the drug to move through. The swellable agents include cellulose wicking agents, and osmogents such as lactose (col. 5, lin. 60-65). The dosage form is capable of zero-order release of the active agents (col. 7, lin. 30-35). The solid core tablet is a compressed tablet comprising a single layer of the components comprising both the active ingredient components and the swellable composition (Examples). It would have been obvious to include the semipermeable polymer combination to the coating of the '200 formulation in order to provide a more precise release of the drug core.

With these aspects in mind one of ordinary skill in the art would have been motivated to combine the semipermeable coating components of the '694 patent into the surrounding coating of the '200 patent in order to provide a more precise drug release. The artisan would have been motivated since the semipermeable coating of the '694 patent comprises similar cellulose

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polymers found in the '200 patent. The combination of the '200 and 694 patent would provide an orally administrable coating where the coating and a core. By combining the semipermeable polymer combination of the '694 patent into the tablet coating of the '200 patent the core would be surrounded by a water soluble polymer. It would have been obvious to combine the prior art with an expected result of stable coated tablet with a precision release rate, with more control.

Response to Arguments

Applicant's arguments with respect to claims 25-31, 34-40 and 42 have been considered but are moot in view of the new ground(s) of rejection. The combination of the '200 and 694 patent would provide an orally administrable coating where the coating and a core. By combining the semipermeable polymer combination of the '694 patent into the tablet coating of the '200 patent the core would be surrounded by a water soluble polymer.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Thursday 7:00-5:30; every Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MICHAEL G. HARTLEY/
Supervisory Patent Examiner, Art Unit 1618

/MICAHA-PAUL YOUNG/
Examiner, Art Unit 1618